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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/020,541 | 04/26/2002 | Larry A. Wheeler | 17400(BAR) | 1687 |

7590
Carlos A. Fisher
ALLERGAN, INC.
T2-7H
2525 Dupont Drive
Irvine, CA 92612

09/30/2004

EXAMINER

ANGELL, JON E

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| ART UNIT | PAPER NUMBER |
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1635

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/020,541 | Applicant(s) WHEELER ET AL. | |
| | Examiner Jon Eric Angell | Art Unit 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-38 are pending in the application and are addressed herein.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 2, drawn to a method for treating choroidal neovascularization using a protein that is a tyrosine kinase inhibitor, classified in class 514, subclass 2.
- II. Claim 2, 8-12, 35 drawn to a method for treating choroidal neovascularization using PEDF, classified in class 514, subclass 2.
- III. Claims 13-15, drawn to a method for treating choroidal neovascularization using a nucleic acid encoding a tyrosine kinase inhibitor (as the instant claims are dependent on any one of the preceding claims), classified in class 514, subclass 44.
- IV. Claims 13-15, 21, 22, drawn to a method for treating choroidal neovascularization using a nucleic acid encoding a PEDF (as the instant claims are dependent on any one of the preceding claims), classified in class 514, subclass 44.
- V. Claims 36 and 37, drawn to a method for treating choroidal neovascularization using brimonidine, classified in class 514, subclass 2.

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- VI. Claims 36 and 38, drawn to a method for treating choroidal neovascularization using memantine, classified in class 514, subclass 2.
- VII. Claims 17, 23 drawn to a method for preventing cell death induced by PDT wherein the method comprises administering NGF, classified in class 514, subclass 2.
- VIII. Claims 17, 23-26 drawn to a method for preventing cell death induced by PDT wherein the method comprises administering PEDF, classified in class 514, subclass 2.
- IX. Claims 17, 23 drawn to a method for preventing cell death induced by PDT wherein the method comprises administering CNTF, classified in class 514, subclass 2.
- X. Claims 17, 23 drawn to a method for preventing cell death induced by PDT wherein the method comprises administering BDNF, classified in class 514, subclass 2.
- XI. Claims 17, 23 drawn to a method for preventing cell death induced by PDT wherein the method comprises administering brimonidine, classified in class 514, subclass 2.

XII. Claims 17, 23 drawn to a method for preventing cell death induced by PDT wherein the method comprises administering memantine, classified in class 514, subclass 2.

XIII. Claims 32, drawn to a method for preventing cell death induced by PDT wherein the method comprises administering a nucleic acid encoding PEDF, classified in class 514, subclass 44.

Claims 1, 3-7, 33, 34 link(s) the inventions of Groups I, II, III, IV, V and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Additionally (and separately), claims 16, 18-22 link(s) the inventions of Groups VII, VIII, IX, X, XI, XII and XIII. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are unrelated to methods VII-XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Inventions I-VI are drawn to methods of treating a mammal suffering from choroidal neovascularization using a method comprising administering an antiangiogenic compound while Inventions VII-XIII are drawn to a method of protecting ocular neural tissue from damage caused by PDT wherein the method comprises administering a neuroprotectant compound. As such the different methods encompass treating different subjects using different methods steps and with different desired results (e.g., treatment of choroidal neovascularization vs. prevention of cell death)

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions encompass administration of patentably distinct compounds, such as chemical compounds, proteins and nucleic acids. Therefore the different inventions have different modes of operation, different functions, and different effects.

Inventions VII-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions encompass administration of patentably distinct compounds, such as chemical

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compounds, proteins and nucleic acids. Therefore the different inventions have different modes of operation, different functions, and different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each Group is unique, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

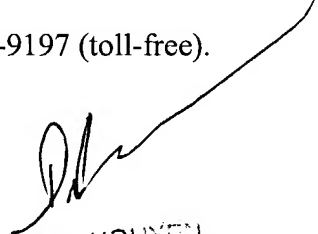
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art unit 1635



DAVET NGUYEN
PRIMARY EXAMINER